Laboratory Management and Quality Assurance

1.0 Principle, Spirit and Intent

The laboratory should carry out its testing activities in such a way as to meet professional standards while satisfying the needs of the contributor and the regulatory authorities or organizations providing recognition. The integrity of the laboratory's procedures, policies, and field and laboratory testing should remain above reproach at all times.

2.0 Purpose and Scope

These guidelines apply to all forensic anthropology laboratories regardless of the number of personnel or the extent of the scope of testing. Practitioners of forensic anthropology, especially sole practitioners, may have varying needs and constraints regarding the forensic anthropology laboratory with which they are associated. Practitioners of forensic anthropology should implement these guidelines to the fullest extent as applicable, practical and appropriate. In the absence of specific guidelines or in the case of conflicting procedures, the principle, spirit and intent should be met.

3.0 General Principles

This document outlines general guidelines and best practices recommended for effective management of a forensic anthropology laboratory and associated activities. A forensic anthropology laboratory is defined as a laboratory involved in the recovery and/or testing of human skeletal remains of medicolegal significance. The overall effectiveness of a forensic anthropology laboratory, balanced with the optimal use of resources, is predicated on sound and established management principles, including a quality assurance program.

4.0 Best Practices

4.1 Defining the Laboratory

The following should be in place and/or defined to establish the institutional nature of the laboratory:

4.1.1 Mission Statement

The laboratory should have a concise statement defining the purpose of the laboratory in relation to its contributors. The mission statement may be generated by the laboratory, its higher headquarters, the establishing or legislative organization responsible for its creation or charter, and/or other body or organization relevant to the laboratory.

4.1.2 Functions

The laboratory should have a list of tasks performed or services provided in order to fulfill its mission. Functions explain how the laboratory achieves it mission and objectives. Functions should support the mission and be reflected in the organization of the laboratory.

4.1.3 Organization

The laboratory should have a clear and unambiguous internal organization and chain of command.

4.1.4 Personnel

The laboratory should define and describe personnel who it employs or utilizes. The authority, responsibilities, and resources of managerial and analytical/technical personnel needed to carry out the laboratory's mission should be defined. The laboratory should maintain current job descriptions to include education, expertise, qualifications and experience required, as well as job responsibilities.

4.2 Code of Ethics

The laboratory should adopt a code of ethics (or however named). The code should address avoidance of involvement in any activities that would diminish confidence in the competence, impartiality, judgment or operational integrity of the laboratory.

4.3 Standard Operating Procedures

The laboratory should write, maintain, and regularly review Standard Operating Procedures (SOPs). SOPs should specify steps and materials used to ensure uniform quality of the process or product. A laboratory's SOPs should contain the following components:

4.3.1 Safety

The laboratory should have, and demonstrate use of, a health and safety program that addresses personal safety, appropriate environmental concerns and compliance. The safety program should minimize, to the greatest possible extent, the risk of accident or

injury and allow the laboratory to operate in a manner that protects its staff, collateral personnel, property and the public at large.

4.3.2 Security

The laboratory should have practices for routine security measures for access to the laboratory building and areas where physical evidence is processed and/or stored (including buildings, rooms, cabinets, lockers, refrigerators). Only authorized individuals should be allowed to enter an evidence storage area unescorted.

4.3.3 Evidence Handling

The laboratory should have policies and procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of items of evidence. These policies should protect the evidence from loss, cross-transfer, contamination or deleterious change, as well as protect the interests of the laboratory and the customer.

4.3.4 Case Management

The laboratory should have a system for managing casework and workflow. This may include reviewing examination requests for appropriateness and probative value prior to examination, assessing the priority of cases, assigning examinations to analytical and/or technical personnel, and handling non-skeletal material and/or evidence that is beyond the scope of the laboratory function

4.3.5 Equipment Calibration, Performance Checking and Maintenance

The laboratory should be furnished with sampling, measurement, and testing equipment and related materials required for the correct performance of its tests. The laboratory should have policies and procedures that address the calibration, performance, and maintenance of its equipment and reference materials used during testing and at recovery scenes. In cases where the laboratory needs to use equipment outside its permanent control, suitable precautions should be taken to ensure the functional accuracy of the equipment, as appropriate.

The laboratory should maintain a list of equipment that requires calibration, performance checking and maintenance including each instrument's serial number or other unique identification, and type or name of instrument. A log of calibration, performance checking, maintenance and instrument repair should also be maintained. Instruments or equipment should not be used for casework if satisfactory calibration, performance and maintenance cannot be achieved.

4.3.6 Standard Tests

The laboratory should have written procedures pertaining to standard tests used and the reporting of results. These procedures should consist of appropriate test methods for all tests performed.

All test methods/procedures used by the laboratory should be considered standard if they have been subjected to external peer review and publication, are recognized by the profession as established, or have been approved following satisfactory results of an internal validation study that has been adequately documented. When feasible, tests should be performed by the practitioner without *a priori* knowledge of potentially biasing information.

The laboratory should archive and store all standard test methods/procedures to include instructions on the use and operation of all relevant equipment, and on the handling and preparation of items being tested, where the absence of such instructions could jeopardize the results of the tests.

4.3.7 Competency and Proficiency Testing

The laboratory should have a program and procedures for competency testing and external and/or internal proficiency testing that evaluates practitioners' capabilities and performance. These procedures should contain a list of testing areas and frequency, and a description of the test evaluation processes. A record of competency and proficiency test examinees and results should be maintained. Corrective action should be taken following unsuccessful tests.

All analytical and technical personnel should complete initial competency tests prior to independently conducting casework. These tests should evaluate the practitioner's capabilities and performance in each area in which he/she will perform casework.

All analytical and technical personnel should complete proficiency tests at regular intervals. These tests may be external or internal and should test the practitioner's capabilities and performance in each area in which he/she routinely performs casework to ensure maintenance of the analyst's skill set. Proficiency tests may also serve as a check of SOPs as well as equipment. Proficiency tests are not recommended for non-routine procedures. Individuals who prepare internal proficiency tests are also subject to testing and should take an external proficiency test or an internal test prepared by another individual.

4.3.8 Preventive and Corrective Action

The laboratory should have preventive action policies and procedures that take a proactive approach to identifying and mitigating problems before they occur. Preventive action may involve analysis of data, including trend and risk analyses, proficiency test results, audit findings and observations, and other quality control data, as appropriate.

Where these are found to be outside pre-defined criteria, planned preventive action should be taken to prevent problems. When improvement opportunities are identified or if preventive action is required, plans should be developed, implemented, and monitored to reduce the likelihood of the occurrence of such non-conformances and to take advantage of the opportunities for improvement. All preventive action should be documented.

The laboratory should also have policies and procedures for implementing corrective action when nonconforming work, departures from the policies and procedures, or problems with technical operations have been identified. The procedure for corrective action should start with cause analysis. Potential causes may include, for example, poor methods or procedures, untrained or unskilled staff, poor equipment maintenance or miscalibration, lack of management involvement or supervision, inadequate supplies, high operations tempo, inadequate facilities, or unrealistic requirements (i.e. operations outside the scope of the laboratory functions). When corrective action is needed, the laboratory should select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. Corrective actions should be to a degree appropriate to the magnitude and risk of the problem. Corrective action may be taken with regard to personnel or technical and non-technical procedures. All corrective action should be documented.

4.3.9 System Audits

The laboratory should have policies and procedures for the conduct of audits. An audit is an inspection used to evaluate or verify any activity related to quality assurance. Audits, which may be internal or external, are conducted with the aim of providing the laboratory with an evaluation of performance against existing standards. Audit policies should include a defined scope and a regular schedule.

4.3.10 Technical and Administrative Reviews

The laboratory should have policies and procedures for regularly scheduled external and/or internal technical and administrative reviews of tests and field reports. A technical review is an evaluation of a test and/or field report and applicable supporting documentation (e.g., analytical notes) for adherence to and consistency with laboratory policies, while administrative reviews focus on editorial correctness. The two reviews may be combined into one process.

4.3.11 Court Testimony Monitoring

Members of the laboratory who testify in deposition or in open court should have their testimony monitored and/or reviewed regularly by a suitable member of the laboratory staff or by a key member of the court, as appropriate, and results should be documented. The laboratory staff should undergo periodic training and/or receive continuing education to this effect.

4.3.12 Satisfaction Assessment

Services provided by the laboratory should be assessed by the contributors who have submitted evidence. This can be accomplished through telephonic conversations, surveys, evaluations, etc., and can assist in determining areas in which the laboratory could potentially improve its services.

4.3.13 Deviations from Standard Procedures

Occasionally, the recovery and testing of skeletal remains requires deviation from established standards. The following should be considered when deviating from standard procedures:

- Where possible, the practitioner should obtain prior approval from the laboratory management to deviate from the standard.
- When it is impractical or impossible to consult laboratory management, the practitioner should exercise professional judgment in a manner designed to best uphold the principle, spirit and intent of the procedures to minimize any adverse impact that may arise from such deviations.
- Deviations from the standard should be adequately documented.